Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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Report Date:11/17/2008

## **Study Summary**

| Laboratory<br>Name   | Study<br>Number        | Study<br>Start<br>Date | Length<br>of<br>Study<br>in Days | Number<br>of Animals<br>Total and<br>(#/Cage) | Number<br>Surviving<br>and (Mean<br>Life Span) | Maximum<br>Mean<br>Weekly Body<br>Weight | Chemical                                     |
|--|------------------------|------------------------|----------------------------------|---|--|--|--|
|  |                        |                        |                                  | M   | ale  |  |  |
| Southern Research Institute<br>Southern Research Institute | 059902408<br>059100508 | 12/16/02<br>07/10/00   | 729<br>729                       | 50 (1)<br>50 (1)                              | 36(687)<br>35(693)                             | 53.8<br>53.6                             | Androstenedione<br>Methylene blue trihydrate |
|  |                        |                        |                                  | Fer   | nale   |  |  |
| Southern Research Institute<br>Southern Research Institute | 059902408<br>059100508 | 12/16/02<br>07/10/00   | 733<br>732                       | 50 (5)<br>50 (5)                              | 35(690)<br>29(695)                             | 65.3<br>63.5                             | Androstenedione<br>Methylene blue trihydrate |

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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|  |           |              | Male        |           |       |              | Female      |          |
|--|-----------|--------------|-------------|-----------|-------|--------------|-------------|----------|
| #All Organs:<br>Benign Tumors          |           |              |             |           |       |              |             |          |
| _                                      |           | 38/50 (76%)  | 37/50 (74%) |           |       | 27/50 (54%)  | 25/50 (50%) |          |
| Overall Incidence                      | Total     | 75/100 (75%) | Mean 75%    | SD 1.41%  | Total | 52/100 (52%) | Mean 52%    | SD 2.83% |
| #All Organs:<br>Malignant Tumors       |           |              |             |           |       |              |             |          |
|  |           | 37/50 (74%)  | 26/50 (52%) |           |       | 27/50 (54%)  | 26/50 (52%) |          |
| Overall Incidence                      | Total     | 63/100 (63%) | Mean 63%    | SD 15.56% | Total | 53/100 (53%) | Mean 53%    | SD 1.41% |
| #All Organs:<br>Malignant and Benign T |           |              |             |           |       |              |             |          |
|  |           | 47/50 (94%)  | 46/50 (92%) |           |       | 40/50 (80%)  | 39/50 (78%) |          |
| Overall Incidence                      | Total     | 93/100 (93%) | Mean 93%    | SD 1.41%  | Total | 79/100 (79%) | Mean 79%    | SD 1.41% |
| #All Organs:<br>Hemangioma             |           |              |             |           |       |              |             |          |
| 0                                      | T-1-1     | 1/50 (2%)    | 0/50 (0%)   | OD 4 440/ | T-1-1 | 1/50 (2%)    | 1/50 (2%)   | OD 00/   |
| Overall Incidence                      | Total     | 1/100 (1%)   | Mean 1%     | SD 1.41%  | Total | 2/100 (2%)   | Mean 2%     | SD 0%    |
| #All Organs:<br>Hemangiosarcoma        |           |              |             |           |       |              |             |          |
|  |           | 5/50 (10%)   | 6/50 (12%)  |           |       | 1/50 (2%)    | 3/50 (6%)   |          |
| Overall Incidence                      | Total     | 11/100 (11%) | Mean 11%    | SD 1.41%  | Total | 4/100 (4%)   | Mean 4%     | SD 2.83% |
| #All Organs:<br>Hemangiosarcoma or H   | emangioma | •••••        |             | •••••     | ••••• |              |             |          |
|  |           | 5/50 (10%)   | 6/50 (12%)  |           |       | 2/50 (4%)    | 4/50 (8%)   |          |
| Overall Incidence                      | Total     | 11/100 (11%) | Mean 11%    | SD 1.41%  | Total | 6/100 (6%)   | Mean 6%     | SD 2.83% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: MICE Strain: B6C3F1 Route: GAVAGE

Vehicle: METHYLCELLULOSE

|   |               |                         | Male                 |          |       |                             | Female                 |           |
|---|---------------|-------------------------|----------------------|----------|-------|-----------------------------|------------------------|-----------|
| #All Organs:<br>Histiocytic Sarcoma                               |               | 0/50 (00/)              | 0/50 (00/)           |          |       | 0/50 /40/                   | 0/50 /40/              |           |
| Overall Incidence   | Total         | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 2/50 (4%)<br>4/100 (4%)     | 2/50 (4%)<br>Mean 4%   | SD 0%     |
|   |               |                         |                      |          |       |                             |                        |           |
| #All Organs:<br>Malignant Lymphoma: h<br>or Undifferentiated Cell |               |                         |                      |          |       | 44/50 (000)                 | 0/50 (400)             |           |
| Overall Incidence   | Total         | 4/50 (8%)<br>6/100 (6%) | 2/50 (4%)<br>Mean 6% | SD 2.83% | Total | 14/50 (28%)<br>20/100 (20%) | 6/50 (12%)<br>Mean 20% | SD 11.31% |
| #All Organs:<br>Mesothelioma: Benign,                             | Malignant, NO |                         | 0/50 (09/)           |          | ••••• | 0/50 (/0//)                 | 0/50 (/0//)            |           |
| Overall Incidence   | Total         | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%)     | 0/50 (0%)<br>Mean 0%   | SD 0%     |
| #All Organs:<br>Mesothelioma: Malignaı                            | nt            | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)                   | 0/50 (0%)              |           |
| Overall Incidence   | Total         | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)                  | Mean 0%                | SD 0%     |
| #All Organs:<br>Osteoma   |               | 0/50 (00)               | 0/50 (00/)           |          |       | 0/50 (00/)                  | 0/50 (00/)             |           |
| Overall Incidence   | Total         | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%)     | 0/50 (0%)<br>Mean 0%   | SD 0%     |
| #All Organs:<br>Osteosarcoma                                      |               | 0/50 (00)               | 0/50 (00/)           |          |       | 4/50 (00)                   | 4/50 (00)              |           |
| Overall Incidence   | Total         | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 1/50 (2%)<br>2/100 (2%)     | 1/50 (2%)<br>Mean 2%   | SD 0%     |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

OII. NOV2000

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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|  |       |                         | Male                 |          |       |                         | Female               |          |
|--|-------|-------------------------|----------------------|----------|-------|-------------------------|----------------------|----------|
| #All Organs:<br>Osteosarcoma or Osteoma      | ı     | -1 ()                   |                      |          |       |                         |                      |          |
| Overall Incidence                            | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 1/50 (2%)<br>2/100 (2%) | 1/50 (2%)<br>Mean 2% | SD 0%    |
| *Adrenal Cortex:<br>Adenoma                  |       | 1/50 (2%)               | 5/48 (10%)           |          |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence                            | Total | 6/98 (6.12%)            | Mean 6.21%           | SD 5.95% | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| *Adrenal Cortex:<br>Sarcoma                  |       |                         |                      |          |       |                         |                      |          |
| Overall Incidence                            | Total | 0/50 (0%)<br>0/98 (0%)  | 0/48 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| *Adrenal Medulla:<br>Pheochromocytoma Benig  |       | 0/49 (0%)               | 0/48 (0%)            |          |       | 0/50 (0%)               | 1/50 (2%)            |          |
| Overall Incidence                            | Total | 0/97 (0%)               | Mean 0%              | SD 0%    | Total | 1/100 (1%)              | Mean 1%              | SD 1.41% |
| *Adrenal Medulla:<br>Pheochromocytoma Comp   | lex   | 0/40 (00/)              | 0/40 (00/)           |          |       | 0/50 (00/)              | 0/50 (00)            |          |
| Overall Incidence                            | Total | 0/49 (0%)<br>0/97 (0%)  | 0/48 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| *Adrenal Medulla:<br>Pheochromocytoma Maligr | nant  |                         |                      |          |       |                         |                      |          |
| Overall Incidence                            | Total | 0/49 (0%)<br>0/97 (0%)  | 0/48 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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| **Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 0/49 (0%) 0/48 (0%) 0/48 (0%) 0/48 (0%) 0/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 0/50 (0 |                   |             |            | Male       |          |       |            | Female     |          |
|--|-------------------|-------------|------------|------------|----------|-------|------------|------------|----------|
| Overall Incidence         Total         0/97 (0%)         Mean 0%         SD 0%         Total         1/100 (1%)         Mean 1%         SD 1.41%           *Bone Marrow: Hemangiosarcoma         0/50 (0%)         1/50 (2%)         0/50 (2%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         SD 0%         SD 0%         Nean 0%         0%         Nean 0%         SD 0%         Nean 0%  |                   | ign, Comple |            | 0/48 (0%)  |          |       | 0/50 (0%)  | 1/50 (2%)  |          |
| Hemangiosarcoma  | Overall Incidence | Total       | ` '        | ` '        | SD 0%    | Total | 1/100 (1%) | Mean 1%    | SD 1.41% |
| Overall Incidence         Total         1/100 (1%)         Mean 1%         SD 1.41%         Total         0/100 (0%)         Mean 0%         SD 0%           *Bone Marrow: Mast Cell Tumor Malignant         0/50 (0%) 0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         SD 0%           Coverall Incidence         Total         0/100 (0%)         Mean 0%         SD 0%         Total 0/100 (0%)         Mean 0%         SD 0%           **Bone: Osteoma         0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%)         Downstream 0/50 (0%) 0/50 (0%)         SD 0%           **Bone: Osteosarcoma           0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%) 0/50 (0%)         Nean 0%         SD 0%  |                   |             | 0/50 (0%)  | 1/50 (29/) |          |       | 0/50 (0%)  | 0/50 (0%)  |          |
| Mast Cell Tumor Malignant  | Overall Incidence | Total       | , ,        | ` '        | SD 1.41% | Total | ` '        | ` '        | SD 0%    |
| Overall Incidence         Total         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)         Mean 0%         SD 0%           #Bone:<br>Hemangiosarcoma         0/50 (0%) 0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%)         SD 0%           Overall Incidence         Total         0/100 (0%) 0/50 (0%) 0/50 (0%)         SD 0%         Total 0/100 (0%) 0/50 (0%) 0/50 (0%)         SD 0%           **Bone: Osteosarcoma           #Bone: Osteosarcoma         0/50 (0%) 0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%)         1/50 (2%) 1/50 (2%)   |                   | nt          | 0/50 (0%)  | 0/50 (0%)  |          |       | 0/50 (0%)  | 0/50 (0%)  |          |
| Hemangiosarcoma  | Overall Incidence | Total       | ` '        | ` '        | SD 0%    | Total | ` ,        | ` '        | SD 0%    |
| Overall Incidence         Total         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)         Mean 0%         SD 0%           #Bone:<br>Osteoma           Overall Incidence         Total         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         Nean 0%         SD 0%           #Bone:<br>Osteosarcoma         0/50 (0%)         0/50 (0%)         0/50 (0%)         1/50 (2%)         1/50 (2%)   |                   |             | 0/50 (0%)  | 0/50 (0%)  |          |       | 0/50 (0%)  | 0/50 (0%)  |          |
| Osteoma  O/50 (0%) O/50 (0%)  Overall Incidence  Total O/100 (0%)  Mean 0%  SD 0%  Total O/100 (0%)  Mean 0%  SD 0%  #Bone: Osteosarcoma  O/50 (0%)  1/50 (2%)  1/50 (2%)  | Overall Incidence | Total       | ` ,        | ` '        | SD 0%    | Total | ()         |            | SD 0%    |
| Overall Incidence         Total         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)         Mean 0%         SD 0%           #Bone:<br>Osteosarcoma           0/50 (0%)         0/50 (0%)         1/50 (2%)         1/50 (2%)         1/50 (2%)   |                   |             | 0/50 (00%) | 0/50 (00/) |          |       | 0/50 (00/) | 0/50 (00/) |          |
| Osteosarcoma 0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%)   | Overall Incidence | Total       | ` ,        | ` '        | SD 0%    | Total | ` ,        | ` '        | SD 0%    |
|  |                   | •••••       | 0/50 (0%)  | 0/50 (0%)  |          |       | 1/50 (2%)  | 1/50 (2%)  |          |
|  | Overall Incidence | Total       | (/         | , ,        | SD 0%    | Total | ` '        | ` ,        | SD 0%    |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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|  |       |                         | Male                 |       |       |                         | Female               |       |
|--|-------|-------------------------|----------------------|-------|-------|-------------------------|----------------------|-------|
| #Bone:<br>Osteosarcoma or Osteoma<br>Overall Incidence | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 1/50 (2%)<br>2/100 (2%) | 1/50 (2%)<br>Mean 2% | SD 0% |
| #Bone:<br>Sarcoma                                      |       | 0/50 (0%)               | 0/50 (0%)            | ••••• |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                                      | Total | 0/30 (0%)               | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0% |
| *Brain: Meningioma Benign Overall Incidence            | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
| *Brain:<br>Meningioma: Benign, Malig                   |       | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                                      | Total | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0% |
| *Brain:<br>Schwannoma Malignant<br>Overall Incidence   | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
| *Clitoral/Preputial Gland:<br>Adenoma                  |       | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/47 (0%)               | 0/48 (0%)            |       |
| Overall Incidence                                      | Total | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/95 (0%)               | Mean 0%              | SD 0% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

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Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

| Length of Study: CHRONIC                              |       |                         |                      |       |       |                        |                      |       |
|---|-------|-------------------------|----------------------|-------|-------|------------------------|----------------------|-------|
|   |       |                         | Male                 |       |       |                        | Female               |       |
| *Clitoral/Preputial Gland:<br>Carcinoma               |       | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/47 (0%)              | 0/48 (0%)            |       |
| Overall Incidence                                     | Total | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/95 (0%)              | Mean 0%              | SD 0% |
| *Clitoral/Preputial Gland:<br>Carcinoma or Adenoma    |       | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/47 (0%)              | 0/48 (0%)            |       |
| Overall Incidence                                     | Total | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/95 (0%)              | Mean 0%              | SD 0% |
| *Clitoral/Preputial Gland:<br>Hemangioma              |       | 0/50 (00/)              | 0/50 (00/)           |       |       | 0/47 (00/)             | 0/40 (00/)           |       |
| Overall Incidence                                     | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/47 (0%)<br>0/95 (0%) | 0/48 (0%)<br>Mean 0% | SD 0% |
| *Clitoral/Preputial Gland:<br>Hemangiosarcoma         |       | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/47 (0%)              | 0/48 (0%)            |       |
| Overall Incidence                                     | Total | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/95 (0%)              | Mean 0%              | SD 0% |
| *Clitoral/Preputial Gland:<br>Squamous Cell Carcinoma |       | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/47 (0%)              | 0/48 (0%)            |       |
| Overall Incidence                                     | Total | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/95 (0%)              | Mean 0%              | SD 0% |
| *Epididymis:<br>Sarcoma                               |       | 0/50 (00/)              | 0/50 (00/)           |       |       |                        |                      |       |
|   |       | 0/50 (0%)               | 0/50 (0%)            |       |       |                        |                      |       |

SD 0% .....

Total

0/100 (0%)

Mean 0%

Overall Incidence

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

|   |       |                            | Male                    |          |       |                             | Female                |          |
|---|-------|----------------------------|-------------------------|----------|-------|-----------------------------|-----------------------|----------|
| #Esophagus:<br>Squamous Cell Carcinoma    | a     |                            |                         |          |       |                             |                       |          |
| Overall Incidence                         | Total | 0/50 (0%)<br>0/100 (0%)    | 0/50 (0%)<br>Mean 0%    | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%)     | 0/50 (0%)<br>Mean 0%  | SD 0%    |
| #Eye:<br>Sarcoma                          | ••••• | 0/50 (00()                 | 0/50 (00/)              |          |       | 0/50 (00/)                  | 0/50 (00/)            |          |
| Overall Incidence                         | Total | 0/50 (0%)<br>0/100 (0%)    | 0/50 (0%)<br>Mean 0%    | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%)     | 0/50 (0%)<br>Mean 0%  | SD 0%    |
| *Gallbladder:<br>Adenoma                  |       | 0/45 /00/)                 | 0/40 (00/)              |          |       | 0/44 (00/)                  | 0/42 (00/)            |          |
| Overall Incidence                         | Total | 0/45 (0%)<br>0/85 (0%)     | 0/40 (0%)<br>Mean 0%    | SD 0%    | Total | 0/44 (0%)<br>0/86 (0%)      | 0/42 (0%)<br>Mean 0%  | SD 0%    |
| #Harderian Gland:<br>Adenoma              |       | 7/50 (14%)                 | 8/50 (16%)              |          |       | 9/50 (18%)                  | 4/50 (8%)             |          |
| Overall Incidence                         | Total | 15/100 (15%)               | Mean 15%                | SD 1.41% | Total | 13/100 (13%)                | Mean 13%              | SD 7.07% |
| #Harderian Gland:<br>Carcinoma            |       | 2/50 (4%)                  | 3/50 (6%)               |          |       | 1/50 (2%)                   | 0/50 (0%)             |          |
| Overall Incidence                         | Total | 5/100 (5%)                 | Mean 5%                 | SD 1.41% | Total | 1/100 (1%)                  | Mean 1%               | SD 1.41% |
| #Harderian Gland:<br>Carcinoma or Adenoma |       | 0/50 (400)                 | 44/50 (000)             |          |       | 40/50 (000)                 | 4/50 (00/)            |          |
| Overall Incidence                         | Total | 9/50 (18%)<br>20/100 (20%) | 11/50 (22%)<br>Mean 20% | SD 2.83% | Total | 10/50 (20%)<br>14/100 (14%) | 4/50 (8%)<br>Mean 14% | SD 8.49% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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|  |       |                         | Male                 |          |       |                         | Female               |       |
|--|-------|-------------------------|----------------------|----------|-------|-------------------------|----------------------|-------|
| #Harderian Gland:<br>Sarcoma                     |       | 0/50 /00/               | 0/50 (00/)           |          |       | 0/50 (00/)              | 0/50 (00/)           |       |
| Overall Incidence                                | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
| *Heart:<br>Hemangioma                            |       | 0/50 (00/)              | 0/50 (00/)           |          |       | 0/50 /00/)              | 0/50 (0%)            |       |
| Overall Incidence                                | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
| *Heart:<br>Hemangiosarcoma                       |       | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                                | Total | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0% |
| *Heart:<br>Sarcoma                               |       | 0/50 (00/)              | 0(50 (00))           |          |       | 0(50 (00))              | 0/50 (00/)           |       |
| Overall Incidence                                | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
| #Intestine Large: Cecum:<br>Carcinoma            |       | 0/50 (00/)              | 1/50 (20/)           |          |       | 0/50 (09/)              | 0/50 (09/)           |       |
| Overall Incidence                                | Total | 0/50 (0%)<br>1/100 (1%) | 1/50 (2%)<br>Mean 1% | SD 1.41% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
| #Intestine Large: Cecum:<br>Carcinoma or Adenoma |       |                         |                      |          |       |                         |                      |       |
| Overall Incidence                                | Total | 0/50 (0%)<br>1/100 (1%) | 1/50 (2%)<br>Mean 1% | SD 1.41% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
|  |       |                         |                      |          |       |                         |                      |       |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Strain: B6C3F1 Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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|   |       |                         | Male                 |          |       |                         | Female               |          |
|---|-------|-------------------------|----------------------|----------|-------|-------------------------|----------------------|----------|
| #Intestine Large: Cecum:<br>Leiomyoma             |       |                         |                      |          |       |                         |                      |          |
| Overall Incidence                                 | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Intestine Large: Cecum:<br>Polyp Adenomatous     |       | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence                                 | Total | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| #Intestine Large: Colon/Rectum:<br>Leiomyosarcoma |       |                         |                      |          |       |                         |                      |          |
| Overall Incidence                                 | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Intestine Small: Duodenum:<br>Adenoma            |       |                         |                      |          |       |                         |                      |          |
| Overall Incidence                                 | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Intestine Small: Duodenum:<br>Carcinoma          | ••••• |                         |                      |          |       |                         |                      |          |
| Overall Incidence                                 | Total | 1/50 (2%)<br>1/100 (1%) | 0/50 (0%)<br>Mean 1% | SD 1.41% | Total | 0/50 (0%)<br>1/100 (1%) | 1/50 (2%)<br>Mean 1% | SD 1.41% |
| #Intestine Small: Duodenum:<br>Leiomyosarcoma     |       |                         |                      |          |       |                         |                      |          |
| Overall Incidence                                 | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

|  |       |                         | Male                 |          |       |                         | Female               |       |
|--|-------|-------------------------|----------------------|----------|-------|-------------------------|----------------------|-------|
| #Intestine Small: Duodenum:<br>Polyp Adenomatous |       | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                                | Total | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0% |
| #Intestine Small: Ileum:<br>Carcinoma            |       | 4/50 /20/\              | 0/50 (0%)            |          |       | 0/50 (09/)              | 0/50 (09/)           |       |
| Overall Incidence                                | Total | 1/50 (2%)<br>1/100 (1%) | 0/50 (0%)<br>Mean 1% | SD 1.41% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
| #Intestine Small: Ileum:<br>Hemangiosarcoma      |       | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                                | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
| #Intestine Small: Ileum:<br>Polyp Adenomatous    |       | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                                | Total | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0% |
| #Intestine Small: Jejunum:<br>Adenoma            |       |                         | 4/50 (004)           |          |       | 0/50 (00/)              | 0/50 (00)            |       |
| Overall Incidence                                | Total | 0/50 (0%)<br>1/100 (1%) | 1/50 (2%)<br>Mean 1% | SD 1.41% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
| #Intestine Small: Jejunum:<br>Carcinoma          |       | 4/50 (00/)              | 0/50 (00/)           |          |       | 0/50 (0%)               | 0/50 (00()           |       |
| Overall Incidence                                | Total | 1/50 (2%)<br>1/100 (1%) | 0/50 (0%)<br>Mean 1% | SD 1.41% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

## Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

|   |        |                         | Male                 |          |       |                         | Female               |          |
|---|--------|-------------------------|----------------------|----------|-------|-------------------------|----------------------|----------|
| #Intestine Small: Jejunum:<br>Hemangiosarcoma   |        |                         |                      |          |       |                         |                      |          |
| Overall Incidence                               | Total  | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Intestine Small: Jejunum:<br>Leiomyosarcoma    |        | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence                               | Total  | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| #Intestine Small: Jejunum:<br>Polyp Adenomatous |        | (20)                    | (201)                |          |       | 0.70                    | (20)                 |          |
| Overall Incidence                               | Total  | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Intestine Small: Site Unspeci                  | ified: | 0/50 (00()              | 4/50 (00/)           |          |       | 0/50 (00/)              | 0/50 (00/)           |          |
| Overall Incidence                               | Total  | 0/50 (0%)<br>1/100 (1%) | 1/50 (2%)<br>Mean 1% | SD 1.41% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Intestine Small: Site Unspeci<br>Carcinoma     | ified: |                         |                      |          |       |                         |                      |          |
| Overall Incidence                               | Total  | 3/50 (6%)<br>3/100 (3%) | 0/50 (0%)<br>Mean 3% | SD 4.24% | Total | 0/50 (0%)<br>1/100 (1%) | 1/50 (2%)<br>Mean 1% | SD 1.41% |
| #Intestine Small: Site Unspeci                  | ified: |                         |                      |          |       | •••••                   | •••••                |          |
| Carcinoma or Adenoma Overall Incidence          | Total  | 3/50 (6%)<br>4/100 (4%) | 1/50 (2%)<br>Mean 4% | SD 2.83% | Total | 0/50 (0%)<br>1/100 (1%) | 1/50 (2%)<br>Mean 1% | SD 1.41% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

|  |        |                         | Male                 |          |       |                           | Female                  |          |
|--|--------|-------------------------|----------------------|----------|-------|---------------------------|-------------------------|----------|
| #Intestine Small: Site Unspec<br>Hemangiosarcoma   | ified: | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)                 | 0/50 (0%)               |          |
| Overall Incidence                                  | Total  | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)                | Mean 0%                 | SD 0%    |
| #Intestine Small: Site Unspec<br>Leiomyosarcoma    | ified: | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)                 | 0/50 (0%)               |          |
| Overall Incidence                                  | Total  | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)                | 0/50 (0%)<br>Mean 0%    | SD 0%    |
| #Intestine Small: Site Unspec<br>Polyp Adenomatous |        | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)                 | 0/50 (0%)               |          |
| Overall Incidence                                  | Total  | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)                | Mean 0%                 | SD 0%    |
| *Islets, Pancreatic:<br>Adenoma                    |        | 2/50 (4%)               | 0/50 (0%)            |          |       | 0/49 (0%)                 | 1/46 (2%)               |          |
| Overall Incidence                                  | Total  | 2/100 (2%)              | Mean 2%              | SD 2.83% | Total | 1/95 (1.05%)              | Mean 1.09%              | SD 1.54% |
| *Islets, Pancreatic:<br>Carcinoma                  |        | (201)                   |                      |          |       |                           | (00)                    |          |
| Overall Incidence                                  | Total  | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/49 (0%)<br>0/95 (0%)    | 0/46 (0%)<br>Mean 0%    | SD 0%    |
| *Islets, Pancreatic:<br>Carcinoma or Adenoma       |        | 0/50 (404)              | 0/50 (00/)           |          |       | 0/40 /00/                 | 4/40 (00%)              |          |
| Overall Incidence                                  | Total  | 2/50 (4%)<br>2/100 (2%) | 0/50 (0%)<br>Mean 2% | SD 2.83% | Total | 0/49 (0%)<br>1/95 (1.05%) | 1/46 (2%)<br>Mean 1.09% | SD 1.54% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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|  |       |                           | Male                    |          |       |                         | Female               |       |
|--|-------|---------------------------|-------------------------|----------|-------|-------------------------|----------------------|-------|
| *Kidney: Renal Tubule:<br>Adenoma              |       |                           |                         |          |       |                         |                      |       |
| Overall Incidence                              | Total | 0/50 (0%)<br>0/99 (0%)    | 0/49 (0%)<br>Mean 0%    | SD 0%    | Total | 0/50 (0%)<br>0/98 (0%)  | 0/48 (0%)<br>Mean 0% | SD 0% |
| *Kidney: Renal Tubule:<br>Carcinoma            |       | 0/50 (00/)                | 4/40 /(20/)             |          |       | 0/50 (00/)              | 0/49 (09/)           |       |
| Overall Incidence                              | Total | 0/50 (0%)<br>1/99 (1.01%) | 1/49 (2%)<br>Mean 1.02% | SD 1.44% | Total | 0/50 (0%)<br>0/98 (0%)  | 0/48 (0%)<br>Mean 0% | SD 0% |
| *Kidney: Renal Tubule:<br>Carcinoma or Adenoma |       | 0/50 (0%)                 | 1/49 (2%)               |          |       | 0/50 (0%)               | 0/48 (0%)            |       |
| Overall Incidence                              | Total | 1/99 (1.01%)              | Mean 1.02%              | SD 1.44% | Total | 0/98 (0%)               | Mean 0%              | SD 0% |
| *Liver:<br>Cholangiocarcinoma                  |       | 0/50 (0%)                 | 0/50 (0%)               |          |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                              | Total | 0/100 (0%)                | Mean 0%                 | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0% |
| *Liver:<br>Fibrous Histiocytoma                |       | 0/50 (0%)                 | 0/50 (0%)               |          |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                              | Total | 0/100 (0%)                | Mean 0%                 | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0% |
| *Liver:<br>Hemangioma                          |       | 4/50 (00/)                | 0/50 (00/)              |          |       | 0/50 (0%)               | 0/50 (00/)           |       |
| Overall Incidence                              | Total | 1/50 (2%)<br>1/100 (1%)   | 0/50 (0%)<br>Mean 1%    | SD 1.41% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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|  |           |                             | Male                    |           |       |                             | Female                  |          |
|--|-----------|-----------------------------|-------------------------|-----------|-------|-----------------------------|-------------------------|----------|
| *Liver: Hemangiosarcoma  Overall Incidence | Total     | 3/50 (6%)<br>5/100 (5%)     | 2/50 (4%)<br>Mean 5%    | SD 1.41%  | Total | 0/50 (0%)<br>0/100 (0%)     | 0/50 (0%)<br>Mean 0%    | SD 0%    |
|  |           | ` ,                         | Modif 070               |           |       | ,                           |                         |          |
| *Liver:<br>Hepatoblastoma                  |           | 3/50 (6%)                   | 2/50 (4%)               |           |       | 0/50 (0%)                   | 0/50 (0%)               |          |
| Overall Incidence                          | Total     | 5/100 (5%)                  | Mean 5%                 | SD 1.41%  | Total | 0/100 (0%)                  | Mean 0%                 | SD 0%    |
| *Liver:<br>Hepatocellular Adenoma          |           |                             |                         |           |       |                             |                         |          |
| Overall Incidence                          | Total     | 32/50 (64%)<br>60/100 (60%) | Mean 60%                | SD 5.66%  | Total | 14/50 (28%)<br>29/100 (29%) | 15/50 (30%)<br>Mean 29% | SD 1.41% |
| *Liver:<br>Hepatocellular Carcinoma        |           |                             |                         |           |       |                             |                         |          |
| Overall Incidence                          | Total     | 26/50 (52%)<br>39/100 (39%) | 13/50 (26%)<br>Mean 39% | SD 18.38% | Total | 5/50 (10%)<br>10/100 (10%)  | 5/50 (10%)<br>Mean 10%  | SD 0%    |
|  |           |                             |                         |           |       |                             |                         |          |
| *Liver:<br>Hepatocellular Carcinoma o      | r Hepatob |                             | (2004)                  |           |       |                             | -(-0(4.004)             |          |
| Overall Incidence                          | Total     | 27/50 (54%)<br>42/100 (42%) | 15/50 (30%)<br>Mean 42% | SD 16.97% | Total | 5/50 (10%)<br>10/100 (10%)  | 5/50 (10%)<br>Mean 10%  | SD 0%    |
| *Liver:<br>Hepatocellular Carcinoma c      |           |                             |                         |           |       | 17/50 (34%)                 | 19/50 (38%)             |          |
| Overall Incidence                          | Total     | 78/100 (78%)                | Mean 78%                | SD 5.66%  | Total | 36/100 (36%)                | Mean 36%                | SD 2.83% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

|  |       |                         | Male                 |          |       |                         | Female               |          |  |
|--|-------|-------------------------|----------------------|----------|-------|-------------------------|----------------------|----------|--|
| *Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma  41/50 (82%) 38/50 (76%) 17/50 (34%) 19/50 (38%) |       |                         |                      |          |       |                         |                      |          |  |
|  |       | 41/50 (82%)             | 38/50 (76%)          |          |       | 17/50 (34%)             | 19/50 (38%)          | 00.000/  |  |
| Overall Incidence  | Total | 79/100 (79%)            | Mean 79%             | SD 4.24% | Total | 36/100 (36%)            | Mean 36%             | SD 2.83% |  |
| *Liver:<br>Hepatocholangiocarcinoma  | a     | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |          |  |
| Overall Incidence  | Total | 0/100 (0%)              | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/30 (0%)               | Mean 0%              | SD 0%    |  |
| *Liver:<br>Ito Cell Tumor Benign   |       | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |          |  |
| Overall Incidence  | Total | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |  |
| *Liver:<br>Ito Cell Tumor Malignant  |       | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |          |  |
| Overall Incidence  | Total | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |  |
| *Liver:<br>Sarcoma   |       | 0/50 /00/               | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (00/)           |          |  |
| Overall Incidence  | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |  |
| *Lung:<br>Adenoma  |       | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |          |  |
| Overall Incidence  | Total | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |  |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

II. NOVZ000

Contract/Lab: All Laboratories

**Species:** MICE **Strain:** B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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|  |                |                            | Male                    |           |   |                         | Female                |          |
|--|----------------|----------------------------|-------------------------|-----------|---|-------------------------|-----------------------|----------|
| Lung:<br>Alveolar/Bronchiolar A            | denoma         | 7/50 /4.40()               | 44/50 (000/)            |           |   | 0/50 /00/               | 4/50 /00/             |          |
| Overall Incidence                          | Total          | 7/50 (14%)<br>18/100 (18%) | 11/50 (22%)<br>Mean 18% | SD 5.66%  | Total                                   | 0/50 (0%)<br>1/100 (1%) | 1/50 (2%)<br>Mean 1%  | SD 1.41% |
|  |                |                            |                         |           |   |                         |                       |          |
| Lung:<br>Alveolar/Bronchiolar C            | arcinoma       |                            |                         |           |   |                         |                       |          |
|  |                | 11/50 (22%)                | 1/50 (2%)               |           |   | 4/50 (8%)               | 5/50 (10%)            |          |
| Overall Incidence                          | Total          | 12/100 (12%)               | Mean 12%                | SD 14.14% | Total                                   | 9/100 (9%)              | Mean 9%               | SD 1.41% |
| Lung:<br>Alveolar/Bronchiolar C<br>Adenoma | arcinoma or Al | veolar/Bronchiolar         |                         |           |   |                         |                       |          |
|  |                | 16/50 (32%)                | 12/50 (24%)             |           |   | 4/50 (8%)               | 6/50 (12%)            |          |
| Overall Incidence                          | Total          | 28/100 (28%)               | Mean 28%                | SD 5.66%  | Total                                   | 10/100 (10%)            | Mean 10%              | SD 2.83% |
| Lung:<br>Fibrosarcoma                      |                | 0/50 (0%)                  | 0/50 (0%)               |           |   | 0/50 (0%)               | 0/50 (0%)             |          |
| Overall Incidence                          | Total          | 0/100 (0%)                 | Mean 0%                 | SD 0%     | Total                                   | 0/100 (0%)              | Mean 0%               | SD 0%    |
| Lung:<br>Fibrous Histiocytoma              | •••••          | 0/50 (0%)                  | 0/50 (0%)               |           | • | 0/50 (0%)               | 0/50 (0%)             |          |
| Overall Incidence                          | Total          | 0/100 (0%)                 | Mean 0%                 | SD 0%     | Total                                   | 0/100 (0%)              | Mean 0%               | SD 0%    |
| Lung:<br>Hemangiosarcoma                   |                | 0/50 (0%)                  | 0/50 (0%)               |           |   | 0/50 (0%)               | 0/50 (0%)             |          |
| Overall Incidence                          | Total          | 0/100 (0%)                 | Mean 0%                 | SD 0%     | Total                                   | 0/100 (0%)              | 0/30 (0 %)<br>Mean 0% | SD 0%    |
| Jverali incluence                          | rotar          | 0/100 (0%)                 | wean 0%                 | 3D 0%     | ıotai                                   | 0/100 (0%)              | wean 0%               | 3D 0%    |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

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Report Date:11/17/2008

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

|  |        |                         | Male                 |       |       |                         | Female               |          |
|--|--------|-------------------------|----------------------|-------|-------|-------------------------|----------------------|----------|
| *Lung:<br>Sarcoma                          |        | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence                          | Total  | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| #Lymph Node:<br>Fibrous Histiocytoma       |        | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence                          | Total  | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| #Lymph Node:<br>Hemangioma                 |        | 0/50 (0%)               | 0/50 (0%)            |       |       | 1/50 (2%)               | 0/50 (0%)            |          |
| Overall Incidence                          | Total  | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 1/100 (1%)              | Mean 1%              | SD 1.41% |
| #Lymph Node:<br>Hemangiosarcoma            | •••••• | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence                          | Total  | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| #Lymph Node:<br>Sarcoma                    | •••••  | 0/50 (00()              | 0/50 (00/)           |       | ••••• | 0/50 (00()              | 0/50 (00/)           |          |
| Overall Incidence                          | Total  | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Lymph Node, Bronchial:<br>Hemangiosarcoma | •••••  | 0/50 (00/)              | 0(50 (004)           |       | ••••  | 0/50 (00/)              | 0/50 (00()           |          |
| Overall Incidence                          | Total  | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: MICE Strain: B6C3F1 Route: GAVAGE

Vehicle: METHYLCELLULOSE

|   |       |                         | Male                 |       |       |                         | Female               |       |
|---|-------|-------------------------|----------------------|-------|-------|-------------------------|----------------------|-------|
| #Lymph Node, Mandibular:<br>Fibrous Histiocytoma      |       | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                                     | Total | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0% |
| #Lymph Node, Mandibular:<br>Hemangiosarcoma           | ••••• | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                                     | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
| #Lymph Node, Mandibular:<br>Mast Cell Tumor Malignant | ••••• | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                                     | Total | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0% |
| #Lymph Node, Mesenteric:<br>Fibrous Histiocytoma      |       | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                                     | Total | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0% |
| #Lymph Node, Mesenteric:<br>Hemangioma                |       |                         | 0/50 (09/)           |       |       | 0/50 (09/)              | 0/50 /00/ \          |       |
| Overall Incidence                                     | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
| #Lymph Node, Mesenteric:<br>Hemangiosarcoma           | ••••• | 0/50 (001)              | 0/50 (00())          |       |       | 0/50 (004)              | 0/50 (00/)           |       |
| Overall Incidence                                     | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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|   |           |                         | Male                 |       |       |                         | Female               |          |
|---|-----------|-------------------------|----------------------|-------|-------|-------------------------|----------------------|----------|
| #Mammary Gland:<br>Adenoacanthoma           |           |                         |                      |       |       |                         |                      |          |
| Overall Incidence                           | Total     | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Mammary Gland:<br>Adenoma                  |           | 0/50 (00/)              | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (00/)           |          |
| Overall Incidence                           | Total     | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Mammary Gland:<br>Carcinoma                |           | 0/50 (00()              | 0/50 (00/)           |       |       | 4/50 (00/)              | 0/50 (40)            |          |
| Overall Incidence                           | Total     | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 1/50 (2%)<br>3/100 (3%) | 2/50 (4%)<br>Mean 3% | SD 1.41% |
| #Mammary Gland:<br>Carcinoma or Adenoma     |           | 0/50 (0%)               | 0/50 (0%)            |       |       | 1/50 (2%)               | 2/50 (4%)            |          |
| Overall Incidence                           | Total     | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 3/100 (3%)              | Mean 3%              | SD 1.41% |
| #Mammary Gland:<br>Fibroadenoma             |           | 0/50 (00)               | 0/50 (004)           |       |       | 0/50 (00/)              | 0/50 (00)            |          |
| Overall Incidence                           | Total     | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Mammary Gland:<br>Fibroma, Fibroadenoma or | r Adenoma |                         |                      |       |       |                         |                      |          |
| Overall Incidence                           | Total     | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

# **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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|  |                |                         | Male                 |        |        |                         | Female               |           |
|--|----------------|-------------------------|----------------------|--------|--------|-------------------------|----------------------|-----------|
| #Mammary Gland:<br>Fibroma, Fibroadenoma | , Carcinoma, c |                         |                      |        |        |                         |                      |           |
| Occupation of James                      | T-1-1          | 0/50 (0%)               | 0/50 (0%)            | 00.00/ | T-1-1  | 1/50 (2%)               | 2/50 (4%)            | OD 4 440/ |
| Overall Incidence                        | Total          | 0/100 (0%)              | Mean 0%              | SD 0%  | Total  | 3/100 (3%)              | Mean 3%              | SD 1.41%  |
| #Mesentery:<br>Fibrosarcoma              |                |                         |                      |        |        |                         |                      |           |
| Overall Incidence                        | Total          | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%  | Total  | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%     |
| overall incluence                        | TOLAI          | 0/100 (0%)              | iviean 0%            | 30 0%  | I Olai | 0/100 (0%)              | Wearr 0%             | 30 0%     |
| #Mesentery:<br>Hemangioma                |                | 0/50 (0%)               | 0/50 (0%)            |        |        | 0/50 (0%)               | 0/50 (0%)            |           |
| Overall Incidence                        | Total          | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%  | Total  | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%     |
| overall incluence                        |                | ` ,                     |                      |        |        | ,                       |                      |           |
| Mesentery:<br>Hemangiosarcoma            |                |                         |                      |        |        |                         |                      |           |
| Overall Incidence                        | Total          | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%  | Total  | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%     |
| , verall illeliderice                    | Total          | 0/100 (0/8)             | IVICALI 070          | 3D 076 | Total  | 0/100 (0/8)             | Weall 070            | 3D 070    |
| Mesentery:<br>Sarcoma                    |                |                         |                      |        |        |                         |                      |           |
|  |                | 0/50 (0%)               | 0/50 (0%)            |        |        | 0/50 (0%)               | 0/50 (0%)            |           |
| Overall Incidence                        | Total          | 0/100 (0%)              | Mean 0%              | SD 0%  | Total  | 0/100 (0%)              | Mean 0%              | SD 0%     |
| Nose:<br>Hemangioma                      |                |                         |                      |        |        |                         |                      |           |
| Overell Incidence                        | Tatal          | 0/50 (0%)               | 0/50 (0%)            | CD 00/ | Tatal  | 0/50 (0%)               | 0/50 (0%)            | CD 00/    |
| Overall Incidence                        | Total          | 0/100 (0%)              | Mean 0%              | SD 0%  | Total  | 0/100 (0%)              | Mean 0%              | SD 0%     |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date:11/17/2008

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

|   |                       |                        | Male                    |                |                |                                       | Female                          |                |
|---|-----------------------|------------------------|-------------------------|----------------|----------------|---------------------------------------|---------------------------------|----------------|
| Nose:<br>Mast Cell Tumor Maligi   | nant                  |                        |                         |                |                |                                       |                                 |                |
|   |                       | 0/50 (09               | 6) 0/50 (0%)            |                |                | 0/50 (0%)                             | 0/50 (0%)                       |                |
| verall Incidence  | Total                 | 0/100 (0%)             | Mean 0%                 | SD 0%          | Total          | 0/100 (0%)                            | Mean 0%                         | SD 0%          |
| Oral Cavity (Oral Mucosa,<br>Papilloma Squamous c   |                       | nx, Tooth, Ging        | va):                    |                |                |                                       |                                 |                |
|   |                       | 0/50 (09               | 6) 0/50 (0%)            |                |                | 0/50 (0%)                             | 0/50 (0%)                       |                |
| verall Incidence  | Total                 | 0/100 (0%)             | Mean 0%                 | SD 0%          | Total          | 0/100 (0%)                            | Mean 0%                         | SD 0%          |
|   |                       |                        |                         | •••••          |                | •••••                                 |                                 |                |
| Oral Cavity (Oral Mucosa,<br>Squamous Cell Carcine  |                       | nx, Tooth, Gingi       | va):                    |                |                |                                       |                                 |                |
| - 4   |                       | 0/50 (09               | 6) 0/50 (0%)            |                |                | 0/50 (0%)                             | 0/50 (0%)                       |                |
| verall Incidence  | Total                 | 0/100 (0%)             | Mean 0%                 | SD 0%          | Total          | 0/100 (0%)                            | Mean 0%                         | SD 0%          |
| Oral Cavity (Oral Mucosa,   | , Tongue, Phary       |                        | va):                    |                |                |                                       |                                 |                |
| Squamous Cell Carcino<br>Papilloma  | oma, Papilloma        | •                      | () 0/50 (0%)            |                |                | 0/50 (0%)                             | 0/50 (0%)                       |                |
| Papilloma   | oma, Papilloma  Total | 0/50 (0%)              | %) 0/50 (0%)<br>Mean 0% | SD 0%          | Total          | 0/50 (0%)<br>0/100 (0%)               | 0/50 (0%)<br>Mean 0%            | SD 0%          |
| Papilloma<br>verall Incidence   |                       | 0/50 (09               | , ,                     | SD 0%          | Total          | ` ,                                   | ` '                             | SD 0%          |
| Papilloma verall Incidence Oral Mucosa:   | Total                 | 0/50 (09               | , ,                     | SD 0%          | Total          | ` ,                                   | ` '                             | SD 0%          |
| Papilloma<br>verall Incidence   | Total                 | 0/50 (09<br>0/100 (0%) | Mean 0%                 | SD 0%          | Total          | 0/100 (0%)                            | Mean 0%                         | SD 0%          |
| Papilloma verall Incidence  Oral Mucosa: Squamous Cell Carcine                              | Total                 | 0/50 (09<br>0/100 (0%) | Mean 0%  0/50 (0%)      |                |                | 0/100 (0%)                            | Mean 0%                         |                |
| Papilloma verall Incidence  Dral Mucosa: Squamous Cell Carcine                              | Total                 | 0/50 (09<br>0/100 (0%) | Mean 0%                 | SD 0%<br>SD 0% | Total<br>Total | 0/100 (0%)                            | Mean 0%                         | SD 0%<br>SD 0% |
| Papilloma  overall Incidence  Oral Mucosa:  Squamous Cell Carcino  overall Incidence        | Total                 | 0/50 (09<br>0/100 (0%) | Mean 0%  0/50 (0%)      |                |                | 0/100 (0%)<br>0/50 (0%)<br>0/100 (0%) | Mean 0%<br>0/50 (0%)<br>Mean 0% |                |
| Papilloma  Overall Incidence  Oral Mucosa: Squamous Cell Carcino  Overall Incidence  Ovary: | Total                 | 0/50 (09<br>0/100 (0%) | Mean 0%  0/50 (0%)      |                |                | 0/100 (0%)                            | Mean 0%                         |                |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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|   | Male |       |                        | Female                  |          |
|---|------|-------|------------------------|-------------------------|----------|
| *Ovary:<br>Cystadenoma                                  |      |       | 4/49 (8%)              | 2/47 (49/)              |          |
| Overall Incidence                                       |      | Total | 6/96 (6.25%)           | 2/47 (4%)<br>Mean 6.21% | SD 2.76% |
| *Ovary:<br>Fibrous Histiocytoma                         |      |       |                        |                         |          |
| Overall Incidence                                       |      | Total | 0/49 (0%)<br>0/96 (0%) | 0/47 (0%)<br>Mean 0%    | SD 0%    |
| *Ovary:   |      |       | •••••                  |                         |          |
| Granulosa Cell Tumor Benign Overall Incidence           |      | Total | 0/49 (0%)<br>0/96 (0%) | 0/47 (0%)<br>Mean 0%    | SD 0%    |
| *Ovary:<br>Granulosa Cell Tumor Malignant               |      |       | 0/49 (0%)              | 0/47 (0%)               |          |
| Overall Incidence                                       |      | Total | 0/96 (0%)              | Mean 0%                 | SD 0%    |
| *Ovary:<br>Granulosa Cell Tumor: Benign, Malignant, NOS |      |       |                        | 0.47 (004)              |          |
| Overall Incidence                                       |      | Total | 0/49 (0%)<br>0/96 (0%) | 0/47 (0%)<br>Mean 0%    | SD 0%    |
| *Ovary:<br>Hemangioma                                   |      |       |                        |                         |          |
| Overall Incidence                                       |      | Total | 0/49 (0%)<br>0/96 (0%) | 0/47 (0%)<br>Mean 0%    | SD 0%    |
|   |      |       |                        |                         |          |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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|                                  | Male |       |                           | Female                  |               |
|----------------------------------|------|-------|---------------------------|-------------------------|---------------|
| *Ovary:<br>Hemangiosarcoma       |      |       |                           |                         |               |
| Overall Incidence                |      | Total | 0/49 (0%)<br>1/96 (1.04%) | 1/47 (2%)<br>Mean 1.06% | SD 1.5%       |
| *Ovary:<br>Leiomyosarcoma        |      |       |                           |                         |               |
| Overall Incidence                |      | Total | 0/49 (0%)<br>0/96 (0%)    | 0/47 (0%)<br>Mean 0%    | SD 0%         |
|                                  |      |       |                           |                         |               |
| *Ovary:<br>Luteoma               |      |       | 0/49 (0%)                 | 0/47 (0%)               | <b>25</b> 200 |
| Overall Incidence                |      | Total | 0/96 (0%)                 | Mean 0%                 | SD 0%         |
| *Ovary:<br>Teratoma Benign       |      |       | 0/49 (0%)                 | 0/47 (0%)               |               |
| Overall Incidence                |      | Total | 0/96 (0%)                 | Mean 0%                 | SD 0%         |
|                                  |      |       |                           |                         |               |
| *Ovary:<br>Teratoma Malignant    |      |       | 0/49 (0%)                 | 0/47 (0%)               |               |
| Overall Incidence                |      | Total | 0/96 (0%)                 | Mean 0%                 | SD 0%         |
|                                  |      |       |                           |                         |               |
| *Ovary:<br>Tubulostromal Adenoma |      |       | 0/49 (0%)                 | 0/47 (0%)               |               |
| Overall Incidence                |      | Total | 0/49 (0%)                 | Mean 0%                 | SD 0%         |
|                                  |      |       |                           |                         |               |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:11/17/2008

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

|   |             |                         | Male                 |       |       |                           | Female                  |          |
|---|-------------|-------------------------|----------------------|-------|-------|---------------------------|-------------------------|----------|
| *Pancreas:  |             |                         |                      |       |       |                           |                         |          |
| Overall Incidence                                       | Total       | 0/50 (0%)<br>0/98 (0%)  | 0/48 (0%)<br>Mean 0% | SD 0% | Total | 0/49 (0%)<br>0/95 (0%)    | 0/46 (0%)<br>Mean 0%    | SD 0%    |
| *Pancreas:<br>Carcinoma                                 |             | 0/50 (09/)              | 0/49 (09/)           |       |       | 0/49 (0%)                 | 0/46 (09/)              |          |
| Overall Incidence                                       | Total       | 0/50 (0%)<br>0/98 (0%)  | 0/48 (0%)<br>Mean 0% | SD 0% | Total | 0/49 (0%)<br>0/95 (0%)    | 0/46 (0%)<br>Mean 0%    | SD 0%    |
| *Pancreas:<br>Carcinoma or Adenoma                      |             |                         |                      |       |       |                           |                         |          |
| Overall Incidence                                       | Total       | 0/50 (0%)<br>0/98 (0%)  | 0/48 (0%)<br>Mean 0% | SD 0% | Total | 0/49 (0%)<br>0/95 (0%)    | 0/46 (0%)<br>Mean 0%    | SD 0%    |
| *Pituitary Gland: Pars Distalis<br>Adenoma              | or Unspecif | ied Site:               |                      |       |       |                           |                         |          |
| Overall Incidence                                       | Total       | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 1/49 (2%)<br>2/95 (2.11%) | 1/46 (2%)<br>Mean 2.11% | SD 0.09% |
| *Pituitary Gland: Pars Distalis<br>Carcinoma            |             |                         |                      | ••••• |       |                           | •••••                   |          |
| Overall Incidence                                       | Total       | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/49 (0%)<br>0/95 (0%)    | 0/46 (0%)<br>Mean 0%    | SD 0%    |
| *Pituitary Gland: Pars Distalis<br>Carcinoma or Adenoma | or Unspecif | ied Site:               |                      | ••••• |       |                           | •••••                   | •••••    |
| Overall Incidence                                       | Total       | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 1/49 (2%)<br>2/95 (2.11%) | 1/46 (2%)<br>Mean 2.11% | SD 0.09% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:11/17/2008

Vehicle: METHYLCELLULOSE

|  |        |                         | Male                 |       |       |                           | Female                  |           |
|--|--------|-------------------------|----------------------|-------|-------|---------------------------|-------------------------|-----------|
| *Pituitary Gland: Pars Intermo                         | edia:  | 0/50 (09/)              | 0/50 (0%)            |       |       | 0/49 (0%)                 | 1/46 (29/)              |           |
| Overall Incidence                                      | Total  | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/49 (0%)<br>1/95 (1.05%) | 1/46 (2%)<br>Mean 1.09% | SD 1.54%  |
|  |        |                         | Mean 076             | 30 0% | Total | 1/95 (1.0576)             | Wealt 1.0976            | 3D 1.3470 |
| *Pituitary Gland: Pars Interme<br>Carcinoma or Adenoma |        |                         |                      |       |       |                           |                         |           |
| Caroniona or Adenoma                                   |        | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/49 (0%)                 | 1/46 (2%)               |           |
| Overall Incidence                                      | Total  | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 1/95 (1.05%)              | Mean 1.09%              | SD 1.54%  |
| *Prostate:<br>Adenoma                                  | •••••• | - ( )                   |                      |       |       |                           |                         |           |
| Overall Incidence                                      | Total  | 0/50 (0%)<br>0/99 (0%)  | 0/49 (0%)<br>Mean 0% | SD 0% |       |                           |                         |           |
| *Prostate:<br>Carcinoma or Adenoma                     |        | 0/50 (0%)               | 0/49 (0%)            |       |       |                           |                         |           |
| Overall Incidence                                      | Total  | 0/99 (0%)               | Mean 0%              | SD 0% |       |                           |                         |           |
| *Prostate:<br>Hemangioma                               | •••••• |                         |                      |       |       |                           |                         |           |
| Overall Incidence                                      | Total  | 0/50 (0%)<br>0/99 (0%)  | 0/49 (0%)<br>Mean 0% | SD 0% |       |                           |                         |           |
| *Salivary Glands:<br>Carcinoma                         |        | 0/50 (004)              | 0(50 (00))           | ••••• |       | 0/40 (00/)                | 0/50 (00/)              | •••••     |
| Overall Incidence                                      | Total  | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/49 (0%)<br>0/99 (0%)    | 0/50 (0%)<br>Mean 0%    | SD 0%     |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

|  |   |                         | Male                 |       |       |                         | Female               |          |
|--|---|-------------------------|----------------------|-------|-------|-------------------------|----------------------|----------|
| *Salivary Glands:<br>Carcinoma or Adenoma      |   |                         |                      |       |       |                         |                      |          |
| Overall Incidence                              | Total                                   | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/49 (0%)<br>0/99 (0%)  | 0/50 (0%)<br>Mean 0% | SD 0%    |
| *Salivary Glands:<br>Mast Cell Tumor Malignant |   | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/49 (0%)               | 0/50 (0%)            |          |
| Overall Incidence                              | Total                                   | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/99 (0%)               | Mean 0%              | SD 0%    |
| #Seminal Vesicle:<br>Adenoma                   |   | 0/50 (0%)               | 0/50 (0%)            |       |       |                         |                      |          |
| Overall Incidence                              | Total                                   | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |       |                         |                      |          |
| #Skeletal Muscle:<br>Fibrosarcoma              |   | 0/50 (0%)               | 0/50 (0%)            |       |       | 1/50 (2%)               | 0/50 (0%)            |          |
| Overall Incidence                              | Total                                   | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 1/100 (1%)              | Mean 1%              | SD 1.41% |
| #Skeletal Muscle:<br>Hemangiosarcoma           |   |                         | 0/50 (0%)            |       |       | 0/50 (0%)               |                      |          |
| Overall Incidence                              | Total                                   | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/100 (0%)              | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Skeletal Muscle:<br>Myxosarcoma               | • | 0/50 (09/)              | 0/50 (09/)           |       |       | 4/50 (20/)              | 0/50 (/0//)          |          |
| Overall Incidence                              | Total                                   | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 1/50 (2%)<br>1/100 (1%) | 0/50 (0%)<br>Mean 1% | SD 1.41% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

|  |            |                         | Male                 |          |       |                         | Female               |          |
|--|------------|-------------------------|----------------------|----------|-------|-------------------------|----------------------|----------|
| #Skeletal Muscle:<br>Rhabdomyosarcoma                  |            | 0/50 (00/)              | 0/50 (00/)           |          |       | 0/50 (00/)              | 0/50 (00/)           |          |
| Overall Incidence                                      | Total      | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Skeletal Muscle:                                      |            |                         |                      |          |       |                         |                      |          |
| Rhabdomyosarcoma or F                                  | Rhabdomyom | a 0/50 (0%)             | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence                                      | Total      | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| #Skeletal Muscle:<br>Sarcoma                           |            |                         |                      |          |       |                         |                      |          |
| Overall Incidence                                      | Total      | 1/50 (2%)<br>1/100 (1%) | 0/50 (0%)<br>Mean 1% | SD 1.41% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Skin:<br>Basal Cell Adenoma or B                      | asosquamou |                         | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence                                      | Total      | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| #Skin:<br>Basal Cell Adenoma, Bas<br>Trichoepithelioma |            | Tumor Benign, or        |                      |          |       |                         |                      |          |
| Overall Incidence                                      | Total      | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Skin:<br>Basal Cell Carcinoma                         |            | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)               | 1/50 (2%)            |          |
| Overall Incidence                                      | Total      | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 1/100 (1%)              | Mean 1%              | SD 1.41% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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|  |                        |  | Male   |       |       |                                      | Female                            |          |  |  |  |
|--|------------------------|--|--|-------|-------|--------------------------------------|-----------------------------------|----------|--|--|--|
| #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)                 |                        |  |  |       |       |                                      |                                   |          |  |  |  |
| ,  |                        | 0/50 (0%)  | 0/50 (0%)                                    |       |       | 0/50 (0%)                            | 1/50 (2%)                         |          |  |  |  |
| Overall Incidence  | Total                  | 0/100 (0%)   | Mean 0%                                      | SD 0% | Total | 1/100 (1%)                           | Mean 1%                           | SD 1.41% |  |  |  |
| Skin:<br>Basal Cell Carcinoma, Bas<br>Tumor (benign, malignant                       | sal Cell Adei          | noma, Basosquamous                                 | 0/50 (0%)                                    |       |       | 0/50 (0%)                            | 1/50 (2%)                         |          |  |  |  |
| Overall Incidence  | Total                  | 0/100 (0%)   | Mean 0%                                      | SD 0% | Total | 1/100 (1%)                           | Mean 1%                           | SD 1.41% |  |  |  |
| Skin:  Basal or Sq. Cell Carcinon or B), Basal Cell Adenoma Papilloma, Keratoacantho | , Adenoma,             | Papilloma, Sq                                      | 0/50 (0%)<br>Mean 0%                         | SD 0% | Total | 0/50 (0%)<br>1/100 (1%)              | 1/50 (2%)<br>Mean 1%              | SD 1.41% |  |  |  |
|  |                        |  |  |       |       |                                      |                                   |          |  |  |  |
| Skin:<br>Basosquamous Tumor Be   |                        | 0/50 (0%)<br>0/100 (0%)                            | 0/50 (0%)<br>Mean 0%                         | SD 0% | Total | 0/50 (0%)<br>0/100 (0%)              | 0/50 (0%)<br>Mean 0%              | SD 0%    |  |  |  |
| Skin:<br>Basosquamous Tumor Be<br>verall Incidence                                   | <b>nign</b><br>Total   | 0/50 (0%)<br>0/100 (0%)                            | 0/50 (0%)<br>Mean 0%                         | SD 0% | Total | 0/50 (0%)<br>0/100 (0%)              | 0/50 (0%)<br>Mean 0%              | SD 0%    |  |  |  |
| Skin:<br>Basosquamous Tumor Be<br>verall Incidence                                   | <b>nign</b><br>Total   | 0/50 (0%)<br>0/100 (0%)                            | 0/50 (0%)<br>Mean 0%                         | SD 0% | Total | 0/50 (0%)<br>0/100 (0%)              | 0/50 (0%)<br>Mean 0%              | SD 0%    |  |  |  |
| Skin: Basosquamous Tumor Be verall Incidence Skin: Fibroma                           | <b>nign</b><br>Total   | 0/50 (0%)<br>0/100 (0%)                            | 0/50 (0%)<br>Mean 0%                         | SD 0% | Total | 0/50 (0%)<br>0/100 (0%)              | 0/50 (0%)<br>Mean 0%              | SD 0%    |  |  |  |
| Skin: Basosquamous Tumor Be Overall Incidence Skin:                                  | nign<br>Total<br>Total | 0/50 (0%)<br>0/100 (0%)<br>0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0%<br>0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%)<br>0/50 (0%) | 0/50 (0%)<br>Mean 0%<br>0/50 (0%) | SD 0%    |  |  |  |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

|            |                                 | Male  |   |  |   | Female   |  |
|------------|---------------------------------|---|---|--|---|--|--|
|            | 0/50 (0%)                       | 0/50 (0%)   |   |  | 3/50 (6%)   | 3/50 (6%)  |  |
| Total      | 0/100 (0%)                      | Mean 0%   | SD 0%   | Total  | 6/100 (6%)  | Mean 6%  | SD 0%  |
| Myxosarcom |                                 |   |   |  |   |  |  |
| Total      | 1/50 (2%)<br>2/100 (2%)         | 1/50 (2%)<br>Mean 2%  | SD 0%   | Total  | 5/50 (10%)<br>8/100 (8%)  | 3/50 (6%)<br>Mean 8%   | SD 2.83%   |
| •••••      | 1/50 (2%)                       | 0/50 (0%)   |   |  | 0/50 (0%)   | 0/50 (0%)  |  |
| Total      | 1/100 (1%)                      | Mean 1%   | SD 1.41%  | Total  | 0/100 (0%)  | Mean 0%  | SD 0%  |
| •••••      | 0/50 (0%)                       | 0/50 (0%)   |   |  | 0/50 (0%)   | 1/50 (2%)  |  |
| Total      | 0/100 (0%)                      | Mean 0%   | SD 0%   | Total  | 1/100 (1%)  | Mean 1%  | SD 1.41%   |
| •••••      |                                 |   |   |  |   |  |  |
| Total      | 2/100 (2%)                      | Mean 2%   | SD 0%   | Total  | 2/100 (2%)  | Mean 2%  | SD 0%  |
|            |                                 |   |   |  |   |  |  |
| Total      | 0/50 (0%)                       | Mean 0%   | SD 0%   | Total  | 0/50 (0%)   | 0/50 (0%)<br>Mean 0%   | SD 0%  |
|            | Myxosarcom  Total  Total  Total | Myxosarcoma, or Fibrous  1/50 (2%)  Total 2/100 (2%)  1/50 (2%)  Total 1/100 (1%)  O/50 (0%)  Total 0/100 (0%)  Total 2/100 (2%)  O/50 (0%) | O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0%  Myxosarcoma, or Fibrous  1/50 (2%) 1/50 (2%) Total 2/100 (2%) Mean 2%  1/50 (2%) O/50 (0%) Total 1/100 (1%) Mean 1%  O/50 (0%) O/50 (0%) Total 0/100 (0%) Mean 0%  1/50 (2%) 1/50 (2%) Total 0/100 (0%) Mean 0% | O/50 (0%)         O/50 (0%)           Total         0/100 (0%)         Mean 0%         SD 0%    Myxosarcoma, or Fibrous  1/50 (2%) 1/50 (2%)  Total 2/100 (2%) Mean 2% SD 0%  1/50 (2%) 0/50 (0%)  Total 1/100 (1%) Mean 1% SD 1.41%  O/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0%  1/50 (2%) Total 2/100 (2%) Mean 2% SD 0%  O/50 (0%) 0/50 (0%)  O/50 (0%) 0/50 (0%)  O/50 (0%) 0/50 (0%)  O/50 (0%)  O/50 (0%) 0/50 (0%) | O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% SD 0% Total  Myxosarcoma, or Fibrous  1/50 (2%) 1/50 (2%) Total 2/100 (2%) Mean 2% SD 0% Total  1/50 (2%) O/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total  O/50 (0%) Mean 0% SD 0% Total  1/50 (2%) Total  O/50 (0%) Mean 0% SD 0% Total | O/50 (0%)   O/50 (0%)   O/50 (0%)   SD 0%   Total   O/100 (6%) | Total 0/150 (0%) 0/50 (0%) Mean 0% SD 0% Total 6/100 (6%) 3/50 (6%)  Myxosarcoma, or Fibrous  1/50 (2%) 1/50 (2%) Mean 2% SD 0% Total 8/100 (8%) Mean 8%  Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0%  Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

|  |                                |  | Male                 |          |       |                         | Female               |          |
|--|--------------------------------|--|----------------------|----------|-------|-------------------------|----------------------|----------|
| #Skin:<br>Myxosarcoma<br>Overall Incidence                         | Total                          | 0/50 (0%)<br>0/100 (0%)                        | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 1/50 (2%)<br>1/100 (1%) | 0/50 (0%)<br>Mean 1% | SD 1.41% |
| #Skin:<br>Neural Crest Tumor<br>Overall Incidence                  | Total                          | 0/50 (0%)<br>0/100 (0%)                        | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Skin:<br>Neurofibrosarcoma or Sc<br>Overall Incidence             | :hwannoma (r<br>Total          | malignant or NOS)<br>0/50 (0%)<br>0/100 (0%)   | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Skin: Neurofibrosarcoma, Neur malignant or NOS) Overall Incidence | r <b>ofibroma, or</b><br>Total | Schwannoma (benign,<br>0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Skin:<br>Osteosarcoma<br>Overall Incidence                        | Total                          | 0/50 (0%)<br>0/100 (0%)                        | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Skin:<br>Sarcoma<br>Overall Incidence                             | Total                          | 0/50 (0%)<br>1/100 (1%)                        | 1/50 (2%)<br>Mean 1% | SD 1.41% | Total | 1/50 (2%)<br>1/100 (1%) | 0/50 (0%)<br>Mean 1% | SD 1.41% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date:11/17/2008

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

|  |               |                         | Male                 |       |       |                         | Female               |          |
|--|---------------|-------------------------|----------------------|-------|-------|-------------------------|----------------------|----------|
| #Skin:<br>Schwannoma Malignant                             |               | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence  | Total         | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| #Skin:<br>Squamous Cell Carcinon                           | na            | 0/50 (/0//)             | 0/50 (09/)           |       |       | 0/50 (09/)              | 0/50 (09/)           |          |
| Overall Incidence  | Total         | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Skin:<br>Squamous Cell Carcinon<br>Basosquamous Tumor (i  |               |                         | 0/50 (0%)            |       |       | 0/50 (0%)               | 1/50 (2%)            |          |
| Overall Incidence  | Total         | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 1/100 (1%)              | Mean 1%              | SD 1.41% |
| #Skin:<br>Squamous Cell Papillom                           |               | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence  | Total         | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| #Skin:<br>Squamous Cell Papillom                           | a or Papillom | a 0/50 (0%)             | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence  | Total         | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| #Skin:<br>Squamous Cell Papillom<br>Carcinoma or Keratoaca |               |                         |                      |       |       |                         |                      |          |
| Overall Incidence  | Total         | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

|   |              |                         | Male                 |       |       |                         | Female               | _     |
|---|--------------|-------------------------|----------------------|-------|-------|-------------------------|----------------------|-------|
| #Skin:<br>Squamous Cell Papilloma,              | Papilloma, o |                         | 0/50 /00/\           |       |       | 0/50 (00/)              | 0/50 (00/)           |       |
| Overall Incidence                               | Total        | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
| #Skin:<br>Trichoepithelioma                     |              | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                               | Total        | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0% |
| #Skin: Sebaceous Gland:<br>Adenoma              |              | (00)                    | (201)                |       |       | 0/20 (00)               | (20)                 |       |
| Overall Incidence                               | Total        | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |
| #Skin: Sebaceous Gland:<br>Carcinoma            |              | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                               | Total        | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0% |
| #Skin: Sebaceous Gland:<br>Carcinoma or Adenoma |              | 0/50 (0%)               | 0/50 (0%)            |       |       | 0/50 (0%)               | 0/50 (0%)            |       |
| Overall Incidence                               | Total        | 0/100 (0%)              | Mean 0%              | SD 0% | Total | 0/100 (0%)              | Mean 0%              | SD 0% |
| #Spinal Cord:<br>Meningioma Malignant           |              | 0/50 (00/)              | 0/50 (00()           |       |       | 0/50 (0%)               | 0/50 (00/)           |       |
| Overall Incidence                               | Total        | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

|   |       |                         | Male                 |          |       |                         | Female               |          |
|---|-------|-------------------------|----------------------|----------|-------|-------------------------|----------------------|----------|
| *Spleen:<br>Fibrous Histiocytoma                    |       | 0/50 (0%)               | 0/49 (0%)            |          |       | 0/50 (0%)               | 0/47 (0%)            |          |
| Overall Incidence                                   | Total | 0/99 (0%)               | Mean 0%              | SD 0%    | Total | 0/97 (0%)               | Mean 0%              | SD 0%    |
| *Spleen:<br>Hemangioma                              |       | 0/50 (0%)               | 0/49 (0%)            |          |       | 0/50 (0%)               | 0/47 (0%)            |          |
| Overall Incidence                                   | Total | 0/99 (0%)               | Mean 0%              | SD 0%    | Total | 0/97 (0%)               | Mean 0%              | SD 0%    |
| *Spleen:<br>Hemangiosarcoma                         |       | 1/50 (2%)               | 2/49 (4%)            |          |       | 0/50 (0%)               | 0/47 (0%)            |          |
| Overall Incidence                                   | Total | 3/99 (3.03%)            | Mean 3.04%           | SD 1.47% | Total | 0/97 (0%)               | Mean 0%              | SD 0%    |
| #Stomach, Forestomach:<br>Mast Cell Tumor Malignant |       | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence                                   | Total | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| #Stomach, Forestomach:<br>Squamous Cell Carcinoma   |       | 0/50 (00()              | 0/50 (00/)           |          |       | 0/50 (00/)              | 0/50 (0%)            |          |
| Overall Incidence                                   | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Stomach, Forestomach:<br>Squamous Cell Carcinoma c |       |                         | 0/50 (0%)            |          |       | 1/50 (2%)               | 0/50 (0%)            |          |
| Overall Incidence                                   | Total | 2/100 (2%)              | Mean 2%              | SD 2.83% | Total | 1/100 (1%)              | Mean 1%              | SD 1.41% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

e for Selected Control Animal Ground Route: GAVAGE

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Report Date:11/17/2008

Vehicle: METHYLCELLULOSE

|   |       |                         | Male                 |          |       |                         | Female               |          |
|---|-------|-------------------------|----------------------|----------|-------|-------------------------|----------------------|----------|
| #Stomach, Forestomach:<br>Squamous Cell Papilloma |       | 2/50 (4%)               | 0/50 (0%)            |          |       | 1/50 (2%)               | 0/50 (0%)            |          |
| Overall Incidence                                 | Total | 2/100 (2%)              | Mean 2%              | SD 2.83% | Total | 1/100 (1%)              | Mean 1%              | SD 1.41% |
| #Stomach, Glandular:<br>Adenoma                   |       |                         |                      |          |       |                         |                      |          |
| Overall Incidence                                 | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Stomach, Glandular:<br>Carcinoma                 | ••••• | 0/50 (00/)              | 0/50 (00/)           |          |       | 0/50 (00)               | 0/50 (00/)           |          |
| Overall Incidence                                 | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Stomach, Glandular:<br>Carcinoma or Adenoma      |       | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence                                 | Total | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| *Testes:<br>Adenoma                               | ••••• | 0/50 (0%)               | 0/50 (0%)            |          |       |                         |                      |          |
| Overall Incidence                                 | Total | 0/30 (0%)               | Mean 0%              | SD 0%    |       |                         |                      |          |
| *Testes:<br>Hemangiosarcoma                       |       | 0.50 (00)               | (201)                |          |       |                         |                      |          |
| Overall Incidence                                 | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |       |                         |                      |          |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

|   |         |                         | Male                 |          |       |                           | Female                  |          |
|---|---------|-------------------------|----------------------|----------|-------|---------------------------|-------------------------|----------|
| *Thymus:<br>Thymoma Malignant                   |         | 0/45 (0%)               | 0/38 (0%)            |          |       | 0/47 (0%)                 | 0/43 (0%)               |          |
| Overall Incidence                               | Total   | 0/83 (0%)               | Mean 0%              | SD 0%    | Total | 0/90 (0%)                 | Mean 0%                 | SD 0%    |
| *Thymus:<br>Thymoma: Benign, Maligna            | nt, NOS | 0/45 (0%)               | 0/38 (0%)            |          |       | 0/47 (0%)                 | 0/43 (0%)               |          |
| Overall Incidence                               | Total   | 0/83 (0%)               | Mean 0%              | SD 0%    | Total | 0/90 (0%)                 | Mean 0%                 | SD 0%    |
| *Thyroid Gland:<br>Adenoma                      |         | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)                 | 0/46 (0%)               |          |
| Overall Incidence                               | Total   | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/96 (0%)                 | Mean 0%                 | SD 0%    |
| *Thyroid Gland: C-Cell:<br>Carcinoma            |         | 0/50 (0%)               | 0/50 (0%)            |          |       | 0/50 (0%)                 | 0/46 (0%)               |          |
| Overall Incidence                               | Total   | 0/100 (0%)              | Mean 0%              | SD 0%    | Total | 0/96 (0%)                 | Mean 0%                 | SD 0%    |
| *Thyroid Gland: C-Cell:<br>Carcinoma or Adenoma |         | 0/50 (0%)               | 0/50 (00/)           |          |       | 0/50 (00()                | 0/40 (00/)              |          |
| Overall Incidence                               | Total   | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    | Total | 0/50 (0%)<br>0/96 (0%)    | 0/46 (0%)<br>Mean 0%    | SD 0%    |
| *Thyroid Gland: Follicular Cell:<br>Adenoma     |         | 0/50 (00/)              | 0/50 (00/)           |          |       | 4/50 (000)                | 4/40 (00%)              |          |
| Overall Incidence                               | Total   | 0/50 (0%)<br>3/100 (3%) | 3/50 (6%)<br>Mean 3% | SD 4.24% | Total | 1/50 (2%)<br>2/96 (2.08%) | 1/46 (2%)<br>Mean 2.09% | SD 0.12% |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

Male

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Female

| *Thyroid Gland: Follicular Cell:<br>Carcinoma            |       |   |            |   |       |              |            |   |
|--|-------|---|------------|---|-------|--------------|------------|---|
|  |       | 0/50 (0%)                               | 0/50 (0%)  |   |       | 1/50 (2%)    | 0/46 (0%)  |   |
| Overall Incidence  | Total | 0/100 (0%)                              | Mean 0%    | SD 0%                                   | Total | 1/96 (1.04%) | Mean 1%    | SD 1.41%                                |
|  | ••••• | • |            |   |       | •••••        | •••••      | • |
| *Thyroid Gland: Follicular Cell:<br>Carcinoma or Adenoma |       |   |            |   |       |              |            |   |
|  |       | 0/50 (0%)                               | 3/50 (6%)  |   |       | 2/50 (4%)    | 1/46 (2%)  |   |
| Overall Incidence  | Total | 3/100 (3%)                              | Mean 3%    | SD 4.24%                                | Total | 3/96 (3.12%) | Mean 3.09% | SD 1.29%                                |
| #Tissue NOS:   |       |   |            | • |       |              |            |   |
| Carcinoma  |       | 0/50 (00/)                              | 0/50 (00/) |   |       | 0/50 (00/)   | 0/50 (00/) |   |
|  |       | 0/50 (0%)                               | 0/50 (0%)  | 00.00/                                  |       | 0/50 (0%)    | 0/50 (0%)  | 25. 22/                                 |
| Overall Incidence  | Total | 0/100 (0%)                              | Mean 0%    | SD 0%                                   | Total | 0/100 (0%)   | Mean 0%    | SD 0%                                   |
| #Tissue NOS:<br>Hemangiosarcoma                          |       |   | - 15       |   |       | - /          |            |   |
|  |       | 0/50 (0%)                               | 0/50 (0%)  |   |       | 0/50 (0%)    | 0/50 (0%)  |   |
| Overall Incidence  | Total | 0/100 (0%)                              | Mean 0%    | SD 0%                                   | Total | 0/100 (0%)   | Mean 0%    | SD 0%                                   |
| #Tissue NOS:<br>Schwannoma Malignant                     |       |   |            |   |       |              |            |   |
|  |       | 0/50 (0%)                               | 0/50 (0%)  |   |       | 0/50 (0%)    | 0/50 (0%)  |   |
| Overall Incidence  | Total | 0/100 (0%)                              | Mean 0%    | SD 0%                                   | Total | 0/100 (0%)   | Mean 0%    | SD 0%                                   |
| #Tongue:   | ••••• |   |            | • |       |              |            |   |
| Squamous Cell Carcinoma                                  |       | 0/50 (09/)                              | 0/50 (09/) |   |       | 0/50 (09/)   | 0/50 (09/) |   |
| Overell Institutes                                       | Tatal | 0/50 (0%)                               | 0/50 (0%)  | CD 00/                                  | Tatal | 0/50 (0%)    | 0/50 (0%)  | CD 00/                                  |
| Overall Incidence  | Total | 0/100 (0%)                              | Mean 0%    | SD 0%                                   | Total | 0/100 (0%)   | Mean 0%    | SD 0%                                   |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

|  |       |                           | Male                    |          |       |                         | Female               |       |  |  |
|--|-------|---------------------------|-------------------------|----------|-------|-------------------------|----------------------|-------|--|--|
| #Tongue: Squamous Cell Carcinoma or Papilloma Squamous |       |                           |                         |          |       |                         |                      |       |  |  |
| Overall Incidence                                      | Total | 0/50 (0%)<br>0/100 (0%)   | 0/50 (0%)<br>Mean 0%    | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |  |  |
| #Tongue:<br>Squamous Cell Papilloma                    |       | 0/50 (0%)                 | 0/50 (0%)               |          |       | 0/50 (0%)               | 0/50 (0%)            |       |  |  |
| Overall Incidence                                      | Total | 0/100 (0%)                | Mean 0%                 | SD 0%    | Total | 0/100 (0%)              | Mean 0%              | SD 0% |  |  |
| #Tooth:<br>Odontoma                                    |       | 0/50 (00())               | 0/50 (00/)              |          |       | 0/50 (00)               | 0/50 (00/)           |       |  |  |
| Overall Incidence                                      | Total | 0/50 (0%)<br>0/100 (0%)   | 0/50 (0%)<br>Mean 0%    | SD 0%    | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |  |  |
| *Urinary Bladder:<br>Hemangioma                        |       | 0/50 (0%)                 | 0/48 (0%)               |          |       | 0/50 (0%)               | 0/45 (0%)            |       |  |  |
| Overall Incidence                                      | Total | 0/98 (0%)                 | Mean 0%                 | SD 0%    | Total | 0/95 (0%)               | Mean 0%              | SD 0% |  |  |
| *Urinary Bladder:<br>Hemangiosarcoma                   | ••••• | 0/50 (0%)                 | 1/48 (2%)               |          |       | 0/50 (0%)               | 0/45 (09/)           |       |  |  |
| Overall Incidence                                      | Total | 0/50 (0%)<br>1/98 (1.02%) | 1/48 (2%)<br>Mean 1.04% | SD 1.47% | Total | 0/50 (0%)<br>0/95 (0%)  | 0/45 (0%)<br>Mean 0% | SD 0% |  |  |
| *Urinary Bladder:<br>Sarcoma                           |       | 0/50 (00()                | 0/40 (00/)              |          |       | 0/50 (00)               | 0/45 (00/)           |       |  |  |
| Overall Incidence                                      | Total | 0/50 (0%)<br>0/98 (0%)    | 0/48 (0%)<br>Mean 0%    | SD 0%    | Total | 0/50 (0%)<br>0/95 (0%)  | 0/45 (0%)<br>Mean 0% | SD 0% |  |  |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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|                             | Male |       |                         | Female               |          |
|-----------------------------|------|-------|-------------------------|----------------------|----------|
| #Uterus:<br>Adenoma         |      |       | 0/50 (00/)              | 4/50 (00/)           |          |
| Overall Incidence           |      | Total | 0/50 (0%)<br>1/100 (1%) | 1/50 (2%)<br>Mean 1% | SD 1.41% |
| #Uterus:<br>Carcinoma       |      |       | (201)                   | 0/50 (00)            |          |
| Overall Incidence           |      | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
| #Uterus:<br>Hemangioma      |      |       | 0/50 (0%)               | 0/50 (0%)            |          |
| Overall Incidence           |      | Total | 0/100 (0%)              | Mean 0%              | SD 0%    |
| #Uterus:<br>Hemangiosarcoma |      |       | 0/50 (0%)               | 1/50 (2%)            |          |
| Overall Incidence           |      | Total | 1/100 (1%)              | Mean 1%              | SD 1.41% |
| #Uterus:<br>Leiomyoma       |      |       | 0/50 (0%)               | 1/50 (2%)            |          |
| Overall Incidence           |      | Total | 1/100 (1%)              | Mean 1%              | SD 1.41% |
| #Uterus:<br>Leiomyosarcoma  |      |       |                         |                      |          |
| Overall Incidence           |      | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0%    |
|                             |      |       |                         |                      |          |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Male Female #Uterus: **Polyp Stromal** 0/50 (0%)**Overall Incidence** Total 2/100 (2%) Mean 2% SD 2.83% #Uterus: Sarcoma Stromal 0/50 0/50 (0%)**Overall Incidence** SD 0% Total 0/100 Mean 0% #Uterus: Sarcoma Stromal or Polyp Stromal 2/50 (4%)0/50 (0%)**Overall Incidence** Total 2/100 (2%) Mean 2% SD 2.83% #Uterus: Schwannoma Malignant 0/50 (0%)Total Mean 0% **Overall Incidence** 0/100 (0%) SD 0% **Squamous Cell Carcinoma** 0/50 1/50 **Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% #Vagina: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) SD 0% Total Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| #Zymbal's Gland:<br>Carcinoma            | Male  |                         |                      |       |       | Female                  |                      |       |  |
|--|-------|-------------------------|----------------------|-------|-------|-------------------------|----------------------|-------|--|
|  |       | 0/50 (00/)              | 0/50 (004)           |       |       | 0(50 (004)              | 0/50 (00/)           |       |  |
| Overall Incidence                        | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |  |
| #Zymbal's Gland:<br>Carcinoma or Adenoma |       |                         |                      |       |       |                         |                      | ••••• |  |
| Overall Incidence                        | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% | Total | 0/50 (0%)<br>0/100 (0%) | 0/50 (0%)<br>Mean 0% | SD 0% |  |

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied